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February 21, 2022

Senator James Maroney
Co-Chair
Joint General Law Committee
LOB, Room 2000
Hartford, CT 06106

Representative Michael D'Agostino
Co-Chair
Joint General Law Committee
LOB, Room 3504
Hartford, CT 06106

RE: Senate Bill 121, The Fair Right to Repair Act - Oppose

Dear Chairman Maroney, D'Agostino, and Members of the Committee,

The Advanced Medical Technology Association (AdvaMed), the national association of the world's leading innovators and manufacturers of medical devices, diagnostic products, digital health technologies, and health information systems, shares this letter to respectfully express our opposition to SB 121, the Fair Right to Repair Act. The bill would compromise patient safety by requiring medical device manufacturers to share repair and design information with third-party servicing entities that have not received appropriate training for the sophistication of the technology. We provide the following information to bring these risks and other key issues to your attention and respectfully request that the committee oppose SB 121.

Patient Safety is Paramount

Original Equipment Manufacturers (OEMs) are required to adhere to federal regulations – more specifically the Quality System Regulation (QSR)[1] - that require

sufficient personnel and training to service them, as well as maintenance of service records on the device, maintenance of training records, and reporting of any malfunctions or defects associated with the serviced device. These requirements are extended to anyone authorized by the OEM, including many third-party service providers, who service their medical technology. These regulations help protect patient safety throughout the design, servicing, and repair process and ensure that regulators and manufacturers are made aware of malfunctions, serious injuries, and other issues in a timely fashion.

Non-authorized third-party servicers are not subject to these same requirements. For this reason, there is no reliable mechanism for OEMs to know how many product failures are due to inadequate, unauthorized servicing and repairs. Of note, FDA issued a report documenting more than 4,300 adverse events – including 294 serious injuries and 40 deaths – that could be attributed to unauthorized servicers. This bill would exacerbate the situation by further enabling 'invisible repairs' that are totally unknown to the OEM or the FDA, adding further complexity to tracking and reporting the quality of work by non-authorized third-party servicers.

Access to Service Not Impeded

As touched on previously, OEMs provide extensive training for their employees and typically make this training available to customers and other third-party servicing entities as part of a coordinated repair strategy. The extensive number of available technicians authorized by OEMs has helped to disprove any credible reports of systemic repair shortages – even during the throes of the pandemic – and to ensure patients remain safe during the use of these complex medical technologies. Any intermittent shortages are a function of the global supply chain and impact access to specific parts no matter the purchaser.

Further, purchasers of medical technology often have many options and are in no way required to use an authorized servicer. Purchasers can take advantage of in-house options for servicing or are free to hire any third-party service company they desire. However, the fact remains that, regarding complex medical technology, authorized servicers provide fast, excellent, and high-quality service and repair – saving customers both time and money through reduced downtimes and optimally-functioning technology, ensuring safe and effective devices for patients.

Innovation and Patient Safety Keyed by Intellectual Property Protection

Medical technology OEMs invest significant resources in research and development to bring to market technologies benefiting patients. Unfortunately, this legislation cripples the intellectual property protections guarding patient safety and patient data in addition to harming the protections in their investment by encouraging piracy of proprietary documentation, including documents related to cybersecurity, by purporting to protect intellectual property but instead relying on circular language.

The requirements of the bill state that manufacturers must provide on "fair and reasonable terms, documentation, parts, and tools...training materials and courses relating to the operation, inspection, diagnosis, maintenance, and repair of powered medical equipment." Later it reads that "nothing in this chapter shall be construed to require an original equipment manufacturer to divulge a trade secret...except as necessary to provide documentation, parts, tools, and training courses and materials on fair and reasonable terms." In many cases, these provisions directly conflict. Trade secrets would be among what would be required to be provided under the earlier provision, (i.e., the first provision would force the disclosure of trade secrets to an entity that has no contractual relationship to the OEM to protect the IP. Significant litigation is the likely result under any attempt to enforce either provision.

The forced disclosure of intellectual property to an entity who is not in a contractual relationship with the OEM decimates the security around maintaining its safe and effective operation in addition to compromising patient data, as any individual can start an independent repair business in the state. Since an OEM's proprietary information – process, methods, technical specifications, or designs – could then be sold through sites such as iFixit or other similar forums, incentivizing piracy and discouraging investment in the very medical technology that is improving safety, and dramatically driving down costs, for patients. This legislation would directly increase the risk of malfunctions (when used by untrained servicers) and nefarious cybersecurity hacks, both of which could jeopardize patient safety through improper operation (impacting treatment and diagnosis). Similarly, the forced disclosure of this proprietary information by legislation would facilitate unauthorized access to patient data.

This legislation would also create the incentive to shift many future medical technology offerings to be available only under lease arrangements to ensure patient safety and protect intellectual property, reducing the flexibility and breadth of arrangements available to providers today.

Conclusion

Thank you for considering our perspective on this complicated issue. Our members bear a significant responsibility to the patients, businesses, governments, and individual consumers that depend on them to protect the safety and security of their medical products, as well as the sensitive data that they contain. We are committed to working with the legislature to promote patient safety, digital privacy and security, while resisting unwarranted intervention in the marketplace with one-sized-fits-all mandates that compromise patient safety in the state.

For these reasons, we urge you to oppose SB 121 and look forward to working with you on this legislation throughout session. Thank you and please contact me if you have any questions, rkozyckyj@advamed.org (312) 550-4366.

Sincerely,

Roxolana Kozyckyj
Director, State Government & Regional Affairs
AdvaMed